

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the effect of Core stability exercises with Otago exercises on balance and quality of life in patients with stroke

Protocol summary

Study aim

Determining and Comparing the Effect of Central Stability Exercises with Otago Exercises on Balance and Quality of Life in Patients with Stroke

Design

Clinical trial with control group, with parallel, blinded, randomized, 69 patients

Settings and conduct

By the Ethics Committee on University Research. At the beginning of the study, demographic questionnaires, leaf equilibrium, time-to-go test, and quality of life questionnaire for stroke were completed. Then, after the intervention, leaf balance questionnaire and time-to-go test were completed and the quality of life questionnaire for stroke was completed one month after completion of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age range 40 to 70 years 2. Neurologist diagnoses ischemic stroke 6 months after stroke 4. Patient balance with cut-off score of 32 and below based on leaf balance questionnaire 5. Individual time $14 \leq$ seconds in the timed take-and-go test 6. Ability to walk independently 7. Having the physical ability to participate in exercise based on the opinion of a specialist 8. No Comorbidities (Heart, Pulmonary and Mental Disorders) 9. Consent to participate in the study and sign the informed consent form 10. Patient's previous non-participation in studies similar to current research Exclusion criteria: 1. Research participants can be excluded from the study under any circumstances.

Intervention groups

The three intervention groups consisted of central stabilization exercises, Otago exercises and control groups. In the Central Stability and Otago Exercises group, there are eight sessions of exercise for eight weeks, three times a week, and 5 minutes of cooling off after each session. The control group received no training.

Main outcome variables

Balance and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200107046046N1**

Registration date: **2020-03-21, 1399/01/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-21, 1399/01/02**

Update count: **0**

Registration date

2020-03-21, 1399/01/02

Registrant information

Name

Fatemeh Pirayesh

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Core stability exercises with Otago exercises on balance and quality of life in patients with stroke

Public title

Comparison of the Effect of Central Stability Exercise and Otago Exercise on Stroke

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Neurologist diagnoses ischemic stroke 6 months after stroke Patient balance with cut-off score of 32 and below based on leaf balance questionnaire Individual time $14 \leq$ seconds in the timed test of getting up and going Ability to walk independently Having the physical ability to participate in exercise based on the opinion of a specialist No Comorbidities (Heart, Pulmonary and Mental Disorders) Consent to participate in the study and sign the informed consent form No previous patient participation in studies similar to current research Age range 40 to 70 years

Exclusion criteria:

Research participants can be excluded from the study at any time.

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **69**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible individuals were randomly assigned based on the lottery method in which the number of individuals in each group was placed in a numbered container and randomly selected at the time of referral and divided into 3 groups for exercise. Central stability, auto-training and control will be provided.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yasuj University of Medical Sciences

Street address

Yasuj, Shahid Motahari Blvd., Yasuj University of Medical Sciences

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2020-02-22, 1398/12/03

Ethics committee reference number

IR.YUMS.REC. 1398. 162

Health conditions studied

1

Description of health condition studied

Patients with stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes

1

Description

Balance

Timepoint

Balance at baseline (before intervention) and after baseline

Method of measurement

Berg balance scale (BBS)

2

Description

Quality of life

Timepoint

Quality of life at baseline (before intervention) and one month after baseline

Method of measurement

Stroke Specific Quality Of Life (SSQOL)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Core stability exercises: Includes Gestures: Camel Cat (lean on your hands and knees on the ground. Rotate your back with your abdominal muscles and pelvis held steady. Then let your waist down as you lift your chest up. And arches), four arms and legs (raising one leg and one arm and one leg), cobra (sleeping on the abdomen and placing your head on your hands and lifting your head upwards and then lowering your chest) Lift up to the hip, lying on the back (raising one leg, raising one foot to the side of the hand and then the opposite hand, raising the pair of legs, raising the pair of legs with two hands and raising the pair of legs). With the ball), hamstring stretches on the chair and on the ground, crunch (flat foot, regular, reverse and ball), bridge (assisted and unassisted) and bridging the Swiss ball They will do three sessions per week for eight weeks and will complete a 5 minute cool down after each session.

Category

Rehabilitation

2

Description

Intervention group: Otago exercises: Includes gestures: walking forward (with and without support), heel (with and then without support), lateral walking (with and without support), single leg (with and without support) Backing), getting up from the chair (with two hands, one hand, no hands and with the ball), walking backwards (with backing and then unsupported and finally with the ball), heel walking (with backing and then Unsupported and ultimately with the ball), they walk and rotate around, doing three sessions for eight weeks each week, and doing 5 minutes of cooling down after each session.

Category

Rehabilitation

3

Description

Control group: Non-intervention: This group will not be trained.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Fatemeh Pirayesh

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Shahid Beheshti Hospital, Shahid Mohammad Montazeri Street, Yasuj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yasouj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Fatemeh Pirayesh

Position

MSc Student of Internal Surgery Nursing

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available